GETINGE Castle

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JAN - 2 2001

K003441

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510(k) SUMMARY

Castle® Series 200HC Steam Sterilizer
Model 233HC

Submitted by: Getinge/Castle Inc.
1777 E Henrietta Road
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Contact Person: Frederick R. Catt
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Date prepared: December 19, 2000

Proprietary Name: Castle® Series 200HC Steam Sterilizer
Model 233HC

Common Name: Steam Sterilizer

Device Classification: Steam Sterilizer (80 FLE)

Class II, as listed per 21 CFR 880.6880

Predicate Device: Castle® Series 200 Steam Sterilizer (Powerclave) [K973225]

Description of Device:

The Model 233HC Steam Sterilizer is intended for use in hospital and health care facilities. The product incorporates an update to the control system that provides additional functionality and ease of use to the end user. It includes the added flexibility to adjust cycle parameters, as on previous sterilizer models, and additionally rename and re-sequence the designated sterilization cycles. Available cycles are as follows:

(Continued...)

Full List of Available Cycles for the Model 233HC – up to 12 Total Cycles (w/ P1 - P6 Active)								
(Note: Cycles re-sequencible by qualified Getinge/Castle personnel)								
Factory Set P#	Ref. No.	Cycle Type Prefix	Cycle Type	Exposure Temperature [°F/°C]	Exposure Time [Min.]	Drying Time [Min.]	Drying Type	(Subject Device) -- Factory Set Cycle [233HC]
P3	3	grv	Gravity 1	250/121	30	30	Gravity	Yes
P4	4	grv	Gravity 2	275/135	10	30	Gravity	Yes
--	10	grv	Gravity 2	275/135	10	30	Gravity	Available
--	12	liq	Liquids *	250/121	45	0.75psi/min.	--	Available
--	11	fls	Flash	275/135	3	0	--	Available
P1	1	vac	Prevacuum 1	275/135	3	16	Vacuum	Yes
--	7	vac	Prevacuum 1	275/135	3	16	Vacuum	Available
--	8	vac	Prevacuum 1	275/135	3	16	Vacuum	Available
P2	2	vac	Prevacuum 2	275/135	3	3	Vacuum	Yes
--	9	vac	Prevacuum 2	275/135	3	3	Vacuum	Available
P5	5	vac	Bowie-Dick Test	273/134	3.5	0	Vacuum	Yes
P6	6	lkt	Leak Test	268/131	3	15/5/15**	Vacuum	Yes
Note 1: *Liquid cycles have 8 minute liquid dwell time as factory set parameter.								
Note 2: ** 5 minutes dry, 5 minute dwell, 15 minute timed leak rate test for change in pressure.								

Factory Set Parameters for Model 233HC						
Factory Set Cycle No.	Cycle Prefix	Cycle Type	Exposure Temperature [°F/°C]	Exposure Time [Min.]	Drying Time [Min.]	Drying Type
P1	vac	Prevacuum 1	275/135	3	16	Vacuum
P2	vac	Prevacuum 2	275/135	3	3	Vacuum
P3	grv	Gravity 1	250/121	30	30	Gravity
P4	grv	Gravity 2	275/135	10	30	Gravity
P5	vac	Bowie-Dick Test	273/134	3.5	0	Vacuum
P6	lkt	Leak Test	268/131	3	15/5/15**	Vacuum

Intended Use:

Castle® Series 200HC Steam Sterilizer (Model 233HC) is intended for use by health care facilities and to be used to sterilize wrapped and unwrapped surgical instruments, linens and liquids (liquids not intended for direct patient contact) by means of pressurized steam.

Predicate Device

Castle® Series 200 Steam Sterilizer (Powerclave) [K973225].

Nonclinical Comparisons to Predicate Device

The Series 200HC Steam Sterilizer, Model 233HC, is a new model designation to identify incorporation of various design improvements. This sterilizer is very similar to the Series 200 predicate device. Modifications made from the predicate device include:

- Addition of the "HC" suffix (Health Care facility type intended use).
- Software change to provide a more modular structure.
- From 12 pre-validated cycles, the customer may have a qualified Getinge/Castle representative configure six cycles that best fit the customer's need.
- Ability for qualified Getinge/Castle representatives to add user customized cycle descriptions in addition to the factory set labeling for the six selected cycles.
- Customer ability for user to modify cycle parameters (time and temperature), through password access, to accommodate specific device sterilization cycle requirements.
- Selectable temperature units (°F or °C) and pressure units (psi, kPa, or bar).
- Relocation of steam to chamber inlet and modifications to drain piping.
- Adjustments to password features.
- Lengthened the recovery time from a power failure from 20 to 60 seconds.

Clinical Data:

No clinical data is required for this submission.

Conclusion:

The Castle® Series 200HC Steam Sterilizer, Model 233HC is a substantially equivalent device to that of the predicate device. There have been no substantial changes in technology, intended use of this device. This sterilizer meets the applicable requirements of AAMI ST8, CSA-Z314.7, GGS-1340A and GGS-1343A Standards.

Based on the provided information in this premarket notification, it can be concluded that the subject device is substantial equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 2 2001

Mr. Frederick R. Catt
Senior Regulatory Compliance Engineer
Getinge/Castle, Incorporated
1777 East Henrietta Road
Rochester, New York 14623-3133

Re: K003441
Trade Name: Castle Model 233HC Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: December 19, 2000
Received: December 20, 2000

Dear Mr. Catt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K003441

Device Name: **Castle® Series 200HC Steam Sterilizer (Model 233HC)**

Indications for Use:

Castle® Series 200HC Steam Sterilizer (Model 233HC) is intended for use by health care facilities and to be used to sterilize wrapped and unwrapped surgical instruments, linens and liquids (liquids not intended for direct patient contact) by means of pressurized steam.

Full List of Available Cycles for Series 200HC – up to 12 Total Cycles (w/ P1 - P6 Active)

Ref. No.	Cycle Type	Exposure Temperature [°F/°C]	Exposure Time [Min.]	Drying Time [Min.]	Available and Factory Set P# Cycles [Model 233HC]	Load Configuration *Max. Load vs. Chamber Length* 37 inch	50 inch	61 inch
1	Gravity 1	250/121	30	30	P3	• Double Wrapped Instrument Trays, up to 16 lbs. ea. *10 trays*	*15 trays*	*20 trays*
2	Gravity 2	275/135	10	30	P4	• Fabric Packs *24 packs*	*36 packs*	*48 packs*
3	Gravity 2	275/135	10	30	Available			
4	Liquids *	250/121	45	0.75psi/min.	Available	• Liquid in open or vented containers (up to 1000 mL ea.) *112 containers*	*154 containers*	*196 containers*
5	Flash	275/135	3	0	Available	• Unwrapped Non-Porous Single Instrument Single non-porous instrument • Unwrapped Non-Porous Instrument Trays - up to 16lbs. ea. *10 trays*	*15 trays*	*20 trays*
6	Prevacuum 1	275/135	3	16	P1	• Wrapped Instrument Trays - up to 16lbs. ea. *10 trays*	*15 trays*	*20 trays*
7	Prevacuum 1	275/135	3	16	Available	• Fabric Packs *24 packs*	*36 packs*	*48 packs*
8	Prevacuum 1	275/135	3	16	Available			
9	Prevacuum 2	275/135	3	3	P2	• Fabric Packs *24 packs*	*36 packs*	*48 packs*
10	Prevacuum 2	275/135	3	3	Available			
11	Bowie-Dick Test	273/134	3.5	0	P5	• S.M.A.R.T. Pack (Bowie-Dick Test Pack.) (1 max.)		
12	Leak Test	268/131	3	15/5/15**	P6	• Empty Chamber Test		

Note 1: Qualified Getinge/Castle personnel may reassign (re-sequence) "Available" cycles to P1-P6.
Note 2: Load configurations are based on AAMI ST8, ST37 & ST46 Standards and Guidelines.
Note 3: *The Liquid cycle is not intended for the sterilization of liquid intended for direct patient contact. Liquid cycles have 8 minute liquid dwell time as factory set parameter and the indicated dry time is expressed as a slow exhaust rate.
Note 4: **15 minute dry, 5 minute dwell, 15 minute timed vacuum leak rate test for change in pressure (differential).
NA: Cycle Not Available

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003441